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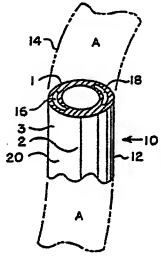
(54) Title: IMPROVED RADIOPAQUE MEDICAL TUBING

(57) Abstract

An improved coextruded tubing (12) composition comprises a physiologically inert flexible waterproof thermoplastic material having encapsulated within the wall (14) of tubing (12) one or more strips (16) of radiopaque material coaxially disposed along the length of tubing.



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IMPROVED RADIOPAQUE MEDICAL TUBING

Background of the invention

This invention relates generally to a radiographic opaque medical tube and more specifically to catheters cannulae and other similar tubes which are introduced into the body cavity during the medical procedures.

Catheters and like cylindrical tubes for introduction to the body cavity are presently manufactured of rubber, vinyl and other thermoplastic materials. Extrusion of such plastic materials is widely employed because of the economies of production. Recently, such tubes have been constructed with an X-ray opaque stripe extending throughout the length of the tube so that by directing a beam of X-rays through the body of the patient, the relative position of the catheter will appear on the fluoroscope or X-ray film. The stripe may include any suitable X-ray opaque pigment such as one of the bismuth salts.

The list of following U.S. patents discloses a wide variety of medical tube constructions having radiopaque properties.

U.S. Patent	Title	Inventors	Issued
2,227,682	Method of Making Striped Pellicles	Ruth Wade	1/7/41
2,237,221	Application of Cellulose Derivatives	Vincent J.Flynn	4/4/41
2,857,915	X-ray Catheter	D. S. Sheridan	10/28/58
3,190,290	Intercostal Catheters	R. D. Alley, et al	6/22/65
3,228,894	Fluoro Carbon Tungsten Members	Norman C. Jackel	1/11/66
3,336,918	Radiopaque Urethane Coated Catheter and Method for Coating Same	Norman C. Jackel	8/22/67

U.S. Patent	Title	Inventors	Issued
3,529,633	X-ray Opaque Tubing Having A Transparent Stripe	V. L. Vaillancourt	9/22/70
3,605,750	X-ray Tip Catheter	D. S. Sheridan, et al	9/20/71
3,618,614	Nontoxic Radiopaque Multi-wall Medical Surgical Tubings	Vincent J. Flynn	11/9/71
3,749,134	Radiographically Opaque Plastic Tubing	Eugene L. Slingluff, et al	7/31/73
3,847,157	Medical Surgical Tube	James C. Caillouette	11/12/74
4,027,659	Radiographic Opaque and Conductive Striped Metal Tubes	E. L. Slingluff	6/7/77
4,105,732	Radiographic Opaque and Conductive Striped Medical Tubes	E. L. Slingluff	8/8/78

French Certificate de Utilite No. 2,188,448

Composite Walled Surgical/Medical Tubing For Wound Drainage Catheters, Etc., With One Layer of Hard Material in Wall
William Warne & Co. Ltd.
7/6/72

South African Patent No. 7303736

Improvements in or Relating to Tubes For Surgical and Medical Purposes
Reginald W. Harrison
3/3/75

In particular, French Certificate de Utilite No. 2,188,448 describes a multi-layer tubing construction in which one of the materials is radiopaque. In one embodiment the catheter may have incorporated therein rods or wires. Similarly the U.S. 3,190,290 of Alley, et al discloses a catheter having a X-ray opaque line embedded longitudinally therein with the opaque line being interrupted by openings in the catheter. Nevertheless, the prior art does not disclose a catheter in which one or more stripes of radiopaque material are totally encapsulated within the catheter material, so as to prevent a contact between the radiopaque material and either liquid flowing through the catheter or the tissue surrounding the catheter upon insertion into the body of the patient.

Accordingly, it is an advantage of the present invention to provide an improved medical surgical tubing construction having one or more stripes of radiopaque material encapsulated therein. It is an additional advantage of the present invention to provide a tubing construction in which a plurality of radiopaque stripes provides the ability to view the tubing through the x-ray equipment while at the same time permitting viewing of the flow of liquids through the tubing in those areas not occupied by radiopaque stripes.

Summary of the invention

The present invention is particularly directed to medical tubes formed of a suitable flexible material and including an integral stripe portion containing radiopaque material. Preferably the tubing is coextruded of a physiologically inert flexible waterproof thermoplastic. The material may be transparent, translucent or opaque depending on the application desired. Encapsulated and coextruded within the body of the tubing are one or more stripes of radiopaque material extending longitudinally along the length of the tubing. In an embodiment where more than one stripe is utilized, the

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stripes are disposed coaxially from each other. Each stripe, preferably occupies an area not greater than 90° of the circumference of the tubing, in order to minimize the use of radiopaque material. However, stripes of greater width are encompassed within the scope of the invention, and may extend anywhere up to 160° of the circumference of the tubing. In one embodiment, each stripe occupies approximately 90° of the circumference of the tubing, with the stripes disposed approximately 180° from the other.

In another embodiment of the invention a multiplicity of radiopaque stripes are disposed within the tubing, with each stripe occupying a cross-sectional area of approximately 45° of the circumference of the tubing. In this case, a number of stripes are utilized in order to provide sufficient radiopaque properties to the tubing. In an additional alternative, a triad of stripes equally spaced from each other and each occupying approximately 90° of the circumference of the tubing, are disposed within the tubing.

In one embodiment, the previously mentioned radiopaque material of which the stripes are composed, comprises between 10 and 30 percent bismuth trioxide by weight, mixed with a clear plastic material and coextruded into the wall of the tubing. Equivalent quantities of barium sulphate or bismuth subcarbonate may also be utilized. It is particularly important, however, that a high concentration of radiopaque material be contained within the stripe, in order to make it sufficiently visible under X-ray. The tubing itself may be constructed of polytetrafluoroethylene, polyfluorinated ethylene/propylene, polyvinylchloride, nylon, polyethylene, polyurethane or polypropylene. Similarly the plastic material in which the radiopaque material is intermixed may also comprise any one of these materials.

The above-listed catheters are preferably made by an extrusion procedure, although other commonly known manufacturing methods may be used. Thus, a multi-orifice

tubular extrusion die is fitted to a double screw extrusion machine or similar device equipped with means for blowing air into the resulting extruded tube through a central opening in the die. The tubular die has a major orifice which is substantially circular in cross-section, formed between the inner wall and outer wall and also has one or more minor orifices which may be substantially circular in cross-section or any other desired shape.

In extruding the tube of which the catheter is formed, the plastic material to create the tube is extruded through the major orifice, while the X-ray opaque pigmented plastic material which form the longitudinal stripe is extruded through the minor orifice.

With the possible exception of that part of the catheter which comprises the tip of the catheter, the catheter should have substantially a uniform wall thickness throughout its length. Such uniformity in wall thickness is obtained by extruding plastic material through the die in varying quantities per unit time, and at the same time, coordinating the rate of withdrawing the tube away from the die, and also introducing air through the die opening so that the air blowing and withdrawal is coordinated with the change in rate of extrusion of plastic material to maintain a substantially constant wall thickness.

Brief description of the drawings.

FIGURE 1 of the drawings is a side view, partially broken away, of an improved radiopaque medical tubing construction.

FIGURE 2 of the drawings is a cross-sectional view of an improved medical tubing showing in particular a stripe of radiopaque material encapsulated within the wall of the tubing.

FIGURE 3 of the drawings is a cutaway view of the improved radiopaque medical tubing shown in FIGURE 1 showing in particular a pair of oppositely disposed stripes

of radiopaque material each occupying a portion of the circumference of the tubing of less than 90°.

FIGURE 4 of the drawings is a cross-sectional view of an improved radiopaque medical tubing construction showing in particular a triad of radiopaque stripes encapsulated within the wall of the tubing.

FIGURE 5 of the drawings is a cross-sectional view of an improved radiopaque medical tubing construction showing in particular a quartet of stripes of radiopaque material radially disposed and encapsulated within the walls of the tubing.

FIGURE 6 of the drawings is a cross-sectional view of an improved radiopaque medical tubing construction showing in particular a single stripe of radiopaque material occupying a cross-sectional portion of approximately 160° of the circumference of the tubing and encapsulated within the wall of the tubing.

FIGURE 7 of the drawings is a cross-sectional view of an improved radiopaque medical tubing construction showing in particular a sextet of radiopaque stripes, radially disposed and encapsulated within the walls of the tubing.

Detailed Description of the preferred embodiment

While this invention is susceptible of embodiment in many different forms, there are shown in the drawings and will herein be described in detail several specific embodiments with the understanding that the present disclosure is to be considered as exemplification of the principles of the invention and is not intended to limit the invention to the embodiments illustrated.

As best seen in FIGURE 1 of the drawings, improved medical tubing construction 10 comprises a tubular portion 12 constructed of a physiologically inert flexible waterproof thermoplastic material. Encapsulated within the wall 14 of the tubular portion 12 are stripes 16 and 18 of radiopaque material which extend coaxially along a tubular portion 12, in substantially parallel

alignment with axis a-a. As best seen in FIGURES 2 and 3 of the drawings, medical tubing 12 may have a single stripe 16 or a pair of stripes 16 and 18 disposed within the wall 14 of tubing 12. Stripes 16 and 18 occupy a cross-sectional area of less than 90° of the circumference of tubing 12 in order to provide, as best seen in FIGURE 1, visibility through the window portions 20 and 22 of tubing 12, when tubing 12 is constructed of a transparent material. This is particularly important when medical tubing 10 is used as a catheter, in that the flashback of blood may be observed through the wall of tubing 12.

While the invention encompasses the use of a single stripe such as stripe 16 seen in FIGURES 2 and 6, it is preferred that a number of stripes, such as stripes 16 and 18 as seen in FIGURE 3 be utilized, in order to provide enhanced radiopaque properties no matter the position of the tubing 12 within the body of the patient. At the same time these considerations must be weighed against the cost of increasing the quantity of radiopaque material encapsulated within the walls of the tubing. Accordingly, a wide variety of configurations of radiopaque stripes encapsulated within the walls of tubing 12 may be utilized.

For example, as seen in FIGURE 2, a single stripe of less than 90° of the circumference of the tubing 12 may be utilized. Alternatively, a pair of stripes each occupying 90° or less of the circumference of tubing 12 may be seen in FIGURE 3. As seen in FIGURE 4, a triad of stripes 16, 18 and 24 may be encapsulated coaxially within tubing 12. In FIGURE 4, stripes 16 and 18 and 24 each occupy less than 45° of the cross-sectional area of tubing 12, but combine to provide the desired degree of radiopacity. Stripes 16, 18 and 24 may be round, square rectangular or any shape required. As best seen in FIGURE 5 of the drawings, a quartet of stripes 16, 18, 24 and 26 may be utilized. Alternatively, as seen in FIGURE 7, a sextet of stripes 16, 18, 24, 26, 28 and 30 may be encapsulated within the wall 14 of tubing 12. The preferred

embodiment of the invention may be seen in FIGURES 1 and 3 in which a pair of radiopaque stripes are coaxially positioned 180° apart from each other.

Of particular significance in the present invention is the enhanced radiopaque properties of the stripes themselves. In order to reduce the cross-sectional area of the stripe an increased degree of loading of radiopaque material must be encapsulated within the tubing. It has been found that a mixture of between 10 and 30% by weight bismuth trioxide, barium sulphate, or bismuth subcarbonate intermixed with physiologically inert thermoplastic material and encapsulated within the tubing provides the desired degree of radiopacity. It has been further found that between 12% and 24% of the aforementioned radiopaque materials (bismuth trioxide or barium sulphate) by weight provide optimum manufacturing and radiopaque properties. Medical tubing 12 may be constructed of such physiologically inert transparent flexible waterproof thermoplastic materials as polytetrafluoroethylene, polyfluorinated ethylene/propylene, polyvinylchloride, nylon, polyethylene, polyurethane or polypropylene. However, the preferred material is polytetrafluoroethylene (Teflon®).

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The foregoing description and drawings merely explain and illustrate the invention and invention is not so limited thereto except insofar as the appended claims are so limited as those skilled in the art who have the disclosure before them will be able to make modifications and variations therein without departing the scope of the invention.

I CLAIM:

1. An improved coextruded medical tubing construction comprising a physiologically inert flexible waterproof thermoplastic material having encapsulated therein a plurality of stripes of radiopaque material coaxially disposed about said tubing.

2. The medical tubing as described in Claim 1 in which each of said stripes of radiopaque material is disposed within a cross-sectional area of approximately 90° of the circumference of said tubing, so as to reduce the quantity of radiopaque material required for radiopacity.

3. The medical tubing as described in Claim 1 or 2 in which said thermoplastic material is substantially transparent so as to permit the observation of the flow of liquid through said tubing between said stripes, while retaining the radiopaque properties of said tubing.

4. The medical tubing as described in Claim 1 in which said plurality of stripes comprises a single stripe of between 30 and 160° of the circumference of said tubing.

5. The medical tubing as described in Claim 1 in which said plurality of stripes comprise a pair of stripes each occupying approximately 90° of the circumference of said tubing, said pair of stripes being oppositely disposed on said tubing.

6. The medical tubing as described in Claim 2 in which each of said stripes is separated from the next by a cross-sectional area of the circumference of said tubing substantially equal to or greater than the cross sectional area of said stripe.

7. The medical tubing as described in Claim 6 in which each of said pair of stripes is disposed within a cross-sectional area of approximately 45° of the circumference of said tubing.

8. The medical tubing as described in Claim 6 in which said plurality of stripes comprises a triad, each separated by a substantially equal cross-sectional area of said tubing.

9. The medical tubing as described in Claim 1 in which said plurality of stripes of radiopaque material comprises a mixture of between 6% and 30% by weight of barium sulfate to a physiologically inert filler material.

10. The medical tubing as described in Claim 1 in which said plurality of stripes of radiopaque material comprises a mixture of between 6% and 30% by weight of bismuth trioxide to a physiologically inert filler material.

11. The medical tubing as described in Claim 1 or 2 in which said plurality of stripes of radiopaque material comprises a mixture of between 6% and 30% bismuth subcarbonate by weight to a physiologically inert filler material.

12. The medical tubing as described in Claim 9 or 10 in which said physiologically inert filler material is selected from the group comprising polytetrafluroethylene, polyfluorinated ethylene-propylene polyvinylchloride, nylon, polyethylene, polyurethane or polypropylene.

13. The medical tubing as described in Claim 1 or 2 in which said physiologically inert flexible waterproof thermoplastic material is selected from the group comprising polytetrafluroethylene, polyfluorinated ethylene-propylene, polyvinylchloride, nylon, polyurethane, polyethylene or polypropylene.

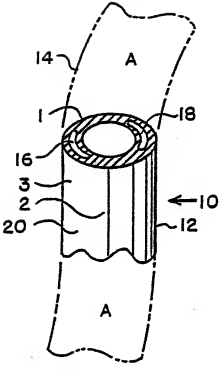

FIG. 1

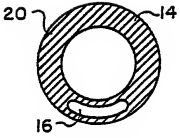

FIG. 2

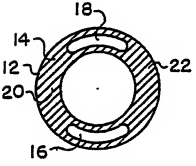

FIG. 3

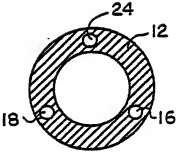

FIG. 4

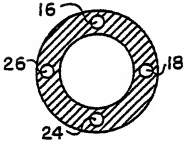

FIG. 5

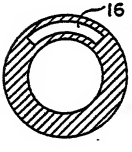

FIG. 6

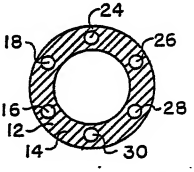

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No PCT/US81/00846

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC [3]

128/348 (US), A61M 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched [4]	
Classification System	Classification Symbols
US	128/348, 349 (all) 214.R, 214.2, 214.4, 350(all).

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [19]
X	US, A, 3,070,132, Published 25 December 1962, Sheridan	1-13
X	US, A, 2,857,915, Published 28 October 1958 Sheridan.	1-13
X	US, A, 3,605,750, Published 20 September 197[illegible] Sheridan et al	1-13

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
12 August 1981	08 OCT 1981
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	R.W. Michell